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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
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ILLINC.266M TRADEMARK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Illumina, Inc.,	)	Opposition No.: 91194218
	)	
Opposer,	)	
	)	
v.	)	
	)	
Meridian Bioscience, Inc.,	)	
	)	
Applicant.	)	
	)	

REPLY BRIEF OF OPPOSER/PLAINTIFF ILLUMINA, INC.

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I. INTRODUCTION

Illumina established that (1) its ILLUMINA registrations and common law use of ILLUMINA predate Meridian's priority date; (2) diagnostic labs commonly create LDTs using the types of goods recited in the ILLUMINA registrations; (3) companies commonly begin selling products labeled Research Use Only ("RUO") and progress to selling FDA-cleared IVD products; (4) many companies sell both research and diagnostic products; and (5) diagnostic labs purchased and used products bearing the ILLUMINA mark before Meridian's priority date.

To the extent Meridian addresses these facts, it presents no meaningful dispute, and often impermissibly limits the parties' recitations. Therefore, Illumina established—for its prior registrations and common law rights—similarity of goods and trade channels. Illumina has also established that diagnostics was within its natural zone of expansion.

This, combined with the similarity of the parties' marks, the fame of the ILLUMINA mark, and that ILLUMINA is a house mark used on a variety of goods and services, establishes a likelihood of confusion. As Illumina explained, purchaser sophistication or lack of reported instances of actual confusion does not outweigh this likelihood.

Meridian's arguments regarding other factors fail. Meridian relies on third-party registrations of ILLUM- and LUMI- formative marks. Meridian, however, fails to show that the goods in those registrations are exposed to the relevant consumer, the extent of any use, or any customer recognition. Therefore, those registrations are irrelevant.

Finally, Meridian relies on the parties' unrelated TRU-formative marks. But Meridian misunderstands the law to which it cites and, in any event, the TRU marks have a descriptive prefix. Thus, they do not, as Meridian contends, "present nearly identical facts."

Therefore, the Board should cancel Meridian's ILLUMIGENE registrations and refuse registration to Meridian's ILLUMIPRO applications.

II. ARGUMENT

A. Illumina has priority

Meridian argues that "it has priority in the clinical diagnostic space" and that "the Board need not even address whether there is a likelihood of confusion." Mer. Br. at 12-13. But Meridian does not dispute that Illumina owns valid prior registrations for ILLUMINA and ILLUMINADX, or that Illumina used ILLUMINA before Meridian's priority date. Therefore, Illumina has established priority. TBMP § 309.03; *L'Oreal S.A. v. Marcon*, 102 USPQ2d 1434, 1436 n. 7 (TTAB 2012).

B. There is a likelihood of confusion between the parties' marks

1. The parties' marks are similar

As Illumina established, (1) the parties' marks are nearly identical in appearance, (2) the suffixes of Meridian's marks are descriptive and connote an association with Illumina's marks and business, and (3) the parties' marks have the same cadence and rhythm, and sound the same. Ill. Br. at 24-26. Therefore, the marks are confusingly similar.

Regarding appearance, Meridian argues that the descriptive "GENE" and "PRO" wording and the informational/laudatory wording "MOLECULAR SIMPLIED" distinguish its marks. Mer. Br. at 14. Meridian also argues that the "X" in ILLUMINADX distinguishes that mark. *Id*. Meridian, however, improperly dissects the marks. *See In re Viterra Inc.*, 101 USPQ2d 1905, 1912 (Fed. Cir. 2012). Viewed as a whole, the ILLUMINA, ILLUMINADX, ILLUMINOTES, ILLUMICODE, ILLUMIGENE and ILLUMIPRO marks are similar in appearance. They share the dominant ILLUMI-prefix and contain virtually the same number of letters.

Besides improperly dissecting the marks, Meridian relies on elements (GENE, PRO and MOLECULAR SIMPLIFIED in its mark and DX in Illumina's mark) that do not differentiate the parties' marks. Each element is weak, if not descriptive. Meridian even recognizes that "MOLECULAR SIMPLIFIED" is subservient. Mer. Br. at 15.

Further, the terms actually strengthen the connection to Illumina. The words "Gene," "Molecules," and "Molecular" appear in the ILLUMINA recitations. The words "Molecular" and "Diagnostics" (a formative of "DX") appear in Meridian's recitations. "PRO" describes the professional nature of Illumina's and Meridian's consumers. Ill. Br. at 26. "SIMPLIFIED" is weak and customers would perceive it as laudatory and informational with no trademark significance. *See* TMEP §§ 1202.04, 1209.03(k).

Regarding sound, Meridian compares the "uh" sound in ILLUMINA to allegedly different sounds in its own marks. Mer. Br. at 15. Meridian again improperly attempts to dissect the marks. It also improperly focuses on the descriptive and subservient "PRO" and "GENE" portion of its marks. *Id*. The marks contain the same number of syllables, and have the same cadence and overall rhythm. Therefore, these minor pronunciation differences are not significant enough to avoid confusion.

Regarding connotation, Meridian cites to a Latin dictionary and notes that "ILLUMINA is Latin for 'enlighten.'" *Id*. Meridian then misleadingly states that "the 'N,' which is present in [Illumina's] mark but absent in Meridian's, is the part of the Latin root giving the word this meaning." *Id*. But Meridian withholds that the same dictionary provides the same meaning for both ILLUMIN and ILLUMI (with no "N"). Thus, both parties' marks share the same Latin root "ILLUMI" and both marks connote the same meaning—to "enlighten."

2. The parties' goods are similar

Illumina showed, and Meridian did not successfully refute, that the parties' goods "are related in some manner." *Weider Publ'ns, LLC v. D & D Beauty Care Co., LLC,* 109 USPQ2d 1347, 1356 (TTAB 2014). This established similarity.

a. The parties' recitations describe similar goods

Both parties' recited goods consist of laboratory equipment and instruments used to analyze or detect DNA. Ill. Br. at 27-31. The ILLUMINA registrations are not all limited to RUO products. *Id*. at 30. Further, labs use RUO products in LDTs to diagnose patients. *Id*. at 13, 30, 34; *see also* Mer. Br. at 2. Meridian does not dispute these facts.

Multiple companies, such as Bayer and Roche, sell both research and diagnostic products. Ill. Br. at 9, 30. Meridian does not appear to dispute this. Illumina itself has also sold both RUO and IVD versions of its BeadXpress and MiSeq products. *Id*. at 11-13, 15-16. Meridian even touts itself as a "fully-integrated life science company" that, in addition to selling diagnostic products, markets its products to research centers. Ex. 401 at 3.

Companies naturally progress from using a technology for research to then using the technology for diagnostics. Ill. Br. at 9, 38. Meridian does not appear to dispute this. Elagin, Meridian's employee, confirms this progression. His previous employer, Third Wave, started in 1994, first sold research products, and sold its first FDA-cleared product in approximately 2004-2005. Elagin Tr. at 25:12-20, 26:20-22. Illumina took a nearly identical amount of time. It was founded in 1998, Ill. Br. at 42, and received FDA clearance in 2010. *Id.* at 12.

b. Illumina's prior use is similar to Meridian's recitations

By 2006, Illumina had established a formal development program to seek FDA clearance for its BeadXpress instrument using the Veracode technology. Ill. Br. at 12. Illumina branded

those products with the ILLUMINA mark. Possemato Decl. ¶ 13. The same year, Illumina started collaborating with other companies to develop diagnostics products in connection with Veracode and BeadXpress. Ill. Br. at 13.

Beginning in 2006, the public learned that Veracode and BeadXpress had diagnostics applications. *Id*. at 12. Illumina gave presentations and disseminated materials to consumers about the technologies' application to diagnostics. *Id*. Illumina also attended trade shows relevant to diagnostics. *Id*. at 12, 17, 18.

When Illumina launched BeadXpress in 2007, clinical laboratories and hospitals began purchasing and using the system in their own LDTs for medical diagnostic purposes. *Id*. at 13. Children's Hospital of Philadelphia ("CHOP") developed a test to diagnose an inherited disease. Illumina publicized CHOP's diagnostic work. *Id*. Similarly, Illumina's customer iGenix developed custom tests. *Id*.

By 2007, Dr. Stephen Young encountered Illumina at conferences. *Id*. at 14. He believed that one of Illumina's technologies would apply to diagnostics. *Id*. at 14-15.

In January 2008, Illumina publicly touted its Diagnostics Business Unit. Illumina created that business unit to support continued expansion in diagnostics and to manage its diagnostics products. *Id*. at 19. In July 2008, Illumina's Board approved a formal diagnostics strategy. Mer. Br. at 24.

By September 2008, Illumina began to create its own CLIA-certified diagnostics services lab, and it completed the lab by the first half of 2009. Ill. Br. at 16. In that lab, Illumina performs diagnostic LDTs for third parties using Illumina's own products. *Id*.

In March 2009, Illumina shipped BeadXpress devices to clinical sites to begin clinical trials for FDA clearance purposes, and it received FDA clearance in April 2010. *Id*. at 12.

Illumina continued to seek and receive FDA clearance for additional products that had previously been sold as RUO products. *Id*. at 16, 41.

These facts establish Illumina's common law rights in diagnostics. At the least, (1) customers' use of Illumina's products for diagnostics, (2) Illumina's collaborations with other companies, and (3) Illumina's presentations that reached diagnostic customers, demonstrate that Illumina's products as registered relate to diagnostics. That Illumina has sold the same product in both RUO and FDA-cleared versions (i.e. BeadXpress and others), also demonstrates that RUO goods are related to IVD goods.

c. Meridian has not overcome Illumina's showing of similarity

i. Meridian's attempts to distinguish Illumina's recitations fail

Meridian argues that Illumina's '507 registration refers to goods "for scientific or medical research," and tries to distinguish diagnostics. Mer. Br. at 16. Meridian then argues that the '703 registration "recites goods that are not in the medical field – they are explicitly limited to 'scientific equipment and instruments.'" *Id*. The '703 recitation does not exclude the medical field. Instead, the '703 recitation includes medical-related terms such as "sequencing DNA" and "genotyping." As Illumina explained, clinical diagnostic laboratories use RUO products in LDTs to diagnose patients. Ill. Br. at 13, 30, 34-35. Therefore, Meridian's distinctions of both the '507 and '703 registrations are irrelevant.

Meridian also argues that Illumina's '539 registration "describes products which are very different from the single-purpose diagnostic kits and readers described in Meridian's recitations." Mer. Br. at 16-17. Meridian does not explain what it means by "single-purpose," why its recitations are limited to single-purpose products, or why the '539 recitation would exclude single-purpose products.

ii. Elagin's testimony does not refute similarity

Meridian turns to Elagin to distinguish the parties' recitations. Mer. Br. at 17. Elagin, however, primarily relies on the alleged research/diagnostics distinction. Elagin Decl. ¶¶ 11-17. As Illumina explained above, that distinction fails. Elagin also attempted to distinguish the type of technology described in the parties' recitations. As explained below, he recanted many of those alleged distinctions during cross examination.

Regarding Illumina's '529 and '703 registrations, Elagin argues that Meridian's recitations differ because the "ILLUMIGENE technology [] utilizes a single analyte amplification and detection by turbidimetry." Elagin Decl. ¶ 14 (discussing '529 registration); *see also id*. ¶ 16 (arguing that turbidity and single-analyte detection distinguish '703 registration). Elagin, however, later retreated from his argument that the ILLUMIGENE recitations are limited to that technology. Elagin Tr. at 59:19-60:4 ("Q. What about the [ILLUMIGENE] recitation of goods … tells you that it is a single analyte amplification? A. It does not. Q. And what about the [ILLUMIGENE] recitation of goods … tells you that it uses turbidemitry [sic]? A. It does not.").

While allegedly distinguishing the '539 registration, Elagin argues that Illumina's consumers are looking for "open-platform research equipment that customers can tweak – certainly RUO products, not IVD products." Elagin Decl. ¶ 14. Elagin, however, conceded that Illumina's consumers may use Illumina's RUO products in an LDT and also separately purchase IVD products. Elagin Tr. at 62:7-16 ("Q. [W]hen you say customers can tweak, does that include using the Illumina product in an LDT? … A. Yes. Q. Do consumers that create LTDs also buy ready-made IVD tests? … A. They could.").

Finally, regarding the '539 registration, Elagin argues that Meridian's recitations do not refer to "random array technology." Elagin Decl. ¶ 14. Elagin, however, admitted that the goods in the ILLUMIGENE recitations could "be used in connection with random array technology." Elagin Tr. at 56:4-11.

iii. Illumina's Section 8 and 15 Affidavits are irrelevant

Meridian argues that Illumina's Section 8 and 15 Affidavits "establish conclusively" that Illumina "entered the diagnostic market only after[]" Meridian's priority date for ILLUMIGENE. Mer. Br. at 10. This makes no sense. That Illumina continuously sold all of the recited products in the ILLUMINA registrations for use in research from 2002-2008 does not preclude that some of those products were also used in diagnostics beginning 2007. Moreover, Meridian improperly attempts to rely on Illumina's actual use to limit the scope of Illumina's recitations. *In re Elbaum*, 211 USPQ 639, 640 (TTAB 1981).

iv. That Illumina marked material "RUO" is irrelevant

Meridian argues that all of Illumina's "products, services, and pieces of supporting marketing material, prior to April 2010, are marked RUO." Mer. Br. at 18. This merely establishes the obvious—that Illumina did not receive FDA clearance until 2010. The RUO label does not refute that the goods cited in the ILLUMINA recitations could be and are used in diagnostic labs in LDTs to diagnose patients, or that diagnostic labs actually purchased and used Illumina products for that purpose. Meridian also notes that, even today, Illumina's website recites a boilerplate "For Research Use Only … except as specifically noted" footer. *Id*. That wording is irrelevant when comparing the parties' recitations. The footer also appears on the

IVD portion of Illumina's website,[1] and it expressly states exceptions to "research use only." This demonstrates that the footer has little probative value.

v. Possemato's testimony does not distinguish the parties' goods

Meridian argues that Possemato distinguished Illumina's BeadXpress product from a third-party (Luminex) product, and that the alleged distinction demonstrates that Illumina's and Meridian's commercial products are also different. Mer. Br. at 19. First, the alleged distinction is irrelevant because Meridian does not connect the supposed distinctions to the parties' recitations. Second, Meridian misrepresents Possemato's testimony. As Illumina explained in its opening brief, and Meridian ignores, Possemato did not testify that the "BeadXpress product offered multi-plexing on the level of 100,000" and was therefore different than Luminex. *Compare* Mer. Br. at 19 *with* Ill. Br. at 31-32. Instead, she testified that the BeadXpress was lower complexity and therefore competitive. Ill Br. at 32.

vi. Diagnostics labs' use of Illumina's products in LDTs is relevant

Meridian wrongly alleges that "the findings of [] LDTs are not meaningful outside of the laboratory that did the analysis." Mer. Br. at 19-20. Meridian misrepresents the document to which it cites. The document explains that labs must validate their own LDTs, and that the "findings of these laboratory-specific analytical **validation[s]** are not meaningful outside of the laboratory that did the analysis."[2] (emphasis added). This merely means that another lab cannot use the same LDT without separately verifying it. It does not mean that the results of the actual

[1] http://www.illumina.com/clinical/diagnostics.html

[2] Meridian cites to http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/. But that page contains a link to another document—"LDT and CLIA FAQs." https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf. Meridian appears to reference the latter document.

diagnostic test are meaningless when reported outside the lab to a physician or patient. The document even explains that LDTs are "*in vitro* diagnostic" tests.

Meridian argues that "the consumer-facing 'output' of an LDT, if any, is a test report issued by the laboratory itself ...." Mer. Br. at 20. Meridian's reference to the "consumer" is misleading. The lab that purchases products to use in LDTs is the relevant consumer—not a physician that orders a test from that lab. Thus, Meridian improperly conflates (1) Illumina's products, which bear Illumina's trademarks and are used by diagnostic labs for LDTs, with (2) reports generated from those LDTs. Therefore, Meridian's arguments that Illumina is merely a component manufacturer, lacks control over the test, and does not appear on the test report, are irrelevant. *Id*. Lab reports generated from Meridian's products do not refer to Meridian either. Kozak Tr. at 138:9-20.

vii. <u>The alleged distinctions between RUOs and IVDs carry little weight</u>

Meridian vaguely contends that "RUO products and IVD products are legally different, both in a vacuum and in the context of an LDT." Mer. Br. at 20. But Meridian never explains or supports its arguments or what "in a vacuum" means. That the FDA distinguishes RUO and IVD goods does not mean that the Board distinguishes the goods for likelihood of confusion purposes. Meridian even admits that RUO products can be used to diagnosis human patients. *Id*. at 2.

Regarding "the context of an LDT," Meridian argues that IVDs are complete products that can be used "right out of the box." *Id*. at 20. Meridian further argues that, "under the relevant regulations," LDTs cannot be built with IVDs. *Id*. Meridian, however, cites no authority, and its alleged distinctions are unpersuasive. The same diagnostic lab could purchase RUO products to construct LDTs and separately purchase IVD products. *See* Rebuttal O'Grady

Decl. ¶¶ 53, 54, Elagin Tr. at 62:7-16. In fact, **the same clinician** often uses both LDTs and IVDs. Rebuttal O'Grady Decl. ¶ 15.

3. Meridian's goods were within Illumina's natural zone of expansion

Illumina has rights to goods that "purchasers might reasonably expect to emanate from it in the normal expansion of its business under the mark." *Mason Eng'g & Design Corp. v. Mateson Chem. Corp.*, 225 USPQ 956, 962 (TTAB 1985).[3] If the Board disagrees that Illumina's evidence establishes similarity of goods, that evidence still establishes that it was reasonable for consumers to expect that diagnostic products (including IVDs) would eventually emanate from a company that makes RUO products. Meridian does not directly dispute that consumers might reasonably expect diagnostic products to emanate from such a company.

Instead, Meridian disputes that Illumina took significant steps to move into diagnostics, and that customers were aware of Illumina's actions. Mer. Br. at 23-29. Illumina, however, need not prove that it actually expanded. *Mason Eng'g, 225* USPQ at 962 (first user is entitled to zone of expansion "whether or not the first user … has actually expanded its use of its mark"). In any event, as explained below, Meridian's argument fails. Illumina had taken such steps before November 2008 and customers were aware of those steps.

Contrary to Meridian's unsupported argument, Illumina's FDA clearance and continued move into diagnostics after November 2008, including the completion of its CLIA lab, also corroborates that diagnostics was within Illumina's zone of expansion. Companies often spend five years or more of internal development before submitting a diagnostic product to the FDA. Heath Decl. ¶ 15. Therefore, evidence dated after November 2008 can help show what Illumina had done and what consumers would have expected before that date.

[3] Meridian wrongly states that Illumina must demonstrate a "strong possibility" of expansion. *See* Mer. Br. at 21.

a. Beginning 2006, Illumina's move into diagnostics was publicized

Meridian ignores or fails to adequately address evidence that informed customers about Illumina's applicability to diagnostics starting in 2006. *See* Ill. Br. at 12-13, 39 (citing Exs. 4, 5, 6, 301, 302, and 313). Meridian does not address Exhibits 5, 6, 301, or 313. Regarding Exhibit 302, Meridian wrongly states that no evidence shows "who attended these presentations (other than [Illumina's] ***internal*** 'sales team')."[4] Mer. Br. at 22, n.14 (emphasis in original). Meridian ignores that Illumina presented the document at industry trade conferences. O'Grady Decl. ¶ 7. Regarding Exhibit 4, the Clinica article, Meridian wrongly contends that it is hearsay and an irrelevant foreign publication. *See* Mer. Br. at 23. Instead, the article demonstrates that the public was informed about Veracode's applicability to diagnostics. *See* Ill. Br. at 12. And as a website, the publication was available in the United States.

b. Illumina's later formal plans confirm its earlier move into diagnostics

Meridian vaguely argues that Illumina's July 2008 Board approval for a formal diagnostic strategy demonstrates that Illumina's prior public announcements about entering diagnostics were "nothing more than trade puffery." Mer. Br. at 24-25. Meridian also argues that Illumina's January 2008 announcement that it created a diagnostic business unit, July 2008 Board approval, and January 2009 announcement of its diagnostics strategy undermine Heath's testimony that Illumina had plans in 2006 to seek FDA approval for the BeadXpress. *Id*. at 25. To the contrary, Illumina's early work in 2006-2007 planted the seeds for what became its more formal plan, which its Board approved in July 2008.

More importantly, the evidence on which Meridian relies to question Illumina's activities in 2006 confirms that, before November 2008, the public was aware that Illumina's zone of

[4] Exhibit 302 is a 2007 presentation entitled "VeraCode Technology – From Research to Molecular Diagnostics." Meridian describes it rather than citing an exhibit number.

expansion included diagnostics. As Meridian admits, in January 2008, Illumina publicly announced that it was creating a diagnostic business unit. Meridian also admits that, in July 2008, Illumina's Board approved a strategy for that unit.

c. Flatley's comments do not contradict that Illumina's products were previously used in diagnostics

Meridian vaguely argues that Illumina's CEO, Jay Flatley, "directly contradict[s] [Illumina's] revisionist history." Mer. Br. at 25. Meridian refers to a 2009 article concerning Illumina's new diagnostics business strategy. The article reported that "Illumina plans to enter the molecular diagnostic market …." Ex. S. Meridian also refers to Flatley's 2010 statement that Illumina's FDA clearance for BeadXpress—the first clearance in company history—was a "transitional step into the diagnostic field." Ex. R.

Flatley's statements about new ways to enter diagnostics do not refute that diagnostics customers previously used Illumina's products in LDTs. Flatley's 2007 published interview, which Meridian ignores, confirms that Illumina already had a diagnostics presence. In that interview, Flatley explained that "[i]n diagnostics, the company is excited to launch its VeraCode technology, which will be offered on the BeadXpress platform." Ex. 5. Thus, O'Grady did not recant her testimony about Illumina's prior diagnostic presence when she testified that, in the 2009 and 2010 documents, Flatley "said something different" than her. *See* Mer. Br. at 24-25. She confirmed that she and Flatley did not disagree, because Flatley discussed Illumina's new strategies to enter diagnostics—not that diagnostics presented a brand new market for Illumina. May 12, 2015 O'Grady Tr. at 103:10-118:3, 222:6-223:4.

d. Illumina developed Veracode under design control

Meridian speculates, based on a false premise, that the document stating that Illumina developed the Veracode products under design control (a precursor to FDA clearance) was "wildly misleading" and "false." Mer. Br. at 26 (discussing Ex. 303). To fashion its guess, Meridian wrongly states that "part of the design control process is something known as 'QSR compliance.'" *Id*. at 26-27. Meridian, however, has it backwards. QSR is not part of design control. Instead, design control is part of QSR. *Compare* 21 CFR § 820.1 (Part 820 of Title 21 is "quality system regulation") *with* 21 CFR § 820.30 (subsection of Part 820 that lists requirements for design control). Therefore, a company could develop a product under design control, but still not be QSR compliant due to other reasons. Further, Illumina's 2009 business plan confirms that Veracode was "developed under design control." Ex. 304 at ILLUM-3447.

Meridian then misrepresents that Illumina was "instructing its field reps to notify its customer base" that Illumina was not developing its products under design control. Mer. Br. at 27. Illumina instructed field reps that, when asked about Illumina's "current regulatory status," they should respond that Illumina is "developing all of the Veracode products under design control and have Design History Files for each of our products." Ex. 303 at ILLUM-0579.

e. Meridian's attack on the Gate's foundation study is unfounded

Meridian argues that the Gates grant proposal "specifically explained that [Illumina's] product 'is designed for research laboratories … [and] has a level of complexity and flexibility inappropriate for the clinical environment' and it needed to be 'adapt[ed] … for clinical use' by the researchers." Mer. Br. at 28 (all ellipses and brackets in original). Meridian's cropped quotation is misleading. The August 2006 proposal stated that the then-current **software package** for the GoldenGate assay was designed for research laboratories, and that the software

was adapted for clinical use by removing features. Ex. 314 at ILLUM-3391. That hardly establishes that Illumina's underlying product was unsuitable to clinical use. The absence of any indication that the **product** had to be adapted for diagnostics suggests that it was suitable.

f. Young's testimony supports Illumina

Meridian misrepresents that Young testified "he 'hoped' [Illumina] would transition to **the clinical diagnostic space**." Mer. Br. at 29 (emphasis added). Young was not discussing whether Illumina was in diagnostics. Instead, he discussed whether, in 2008, Illumina might be focusing on other diseases besides only genetic diseases. Young Tr. at 20:4-21:17. Young hoped that Illumina would move beyond genetic diseases because, as far back as 2007, he thought that Illumina's products "would be relevant … to someone in the infectious disease field." *Id*. at 21:12-17. Even if Meridian were correct, that Young hoped Illumina would transition into diagnostics confirms that consumers believed that diagnostics was within Illumina's natural zone of expansion. This is true even if Young did not believe that Illumina had already begun to expand.

4. Trade channels are similar and overlapping

Diagnostic labs often purchase and use RUO products in LDTs. Ill Br. at 34-35. "[I]t is presumed that … goods would be purchased by all potential customers." *See In re Elbaum*, 211 USPQ at 640. Therefore, even if all of the ILLUMINA registrations were limited to RUO products, and diagnostics labs never purchased Illumina products, the parties' registrations still have overlapping trade channels.

Moreover, diagnostic labs have purchased Illumina's products, and Illumina's marketing efforts include the same trade shows and magazines as Meridian. Ill Br. at 17, 20, 33-34. By

November 2008, diagnostics consumers knew of Illumina's products. In fact, Young, who spoke at a Meridian conference, Elagin Decl. ¶ 44, knew about Illumina in 2007. Young Tr. at 19:7-9.

Faced with this evidence, Meridian misrepresents that LDTs and IVDs are sold into different "sub-channel[s] because the CLIA-lab has ***no use for IVD products***." Mer. Br. at 31 (emphasis in original). Federal law requires that clinical labs performing FDA-cleared tests (i.e. IVDs) classified as "moderate or high complexity" must "have a CLIA certificate."[5] Because Meridian's recitations do not exclude medium or high complexity devices, those recitations include goods that could be sold to a CLIA lab. *See In re Elbaum*, 211 USPQ at 640. Also, the FDA has classified some ILLUMIGENE tests as high complexity.[6] Finally, Kozak, a Meridian employee, contradicted Meridian's allegation that CLIA labs do not use IVDs. Illumina asked whether Meridian would consider "a lab that offers an LDT to test for any disease for which an ILLUMIGENE product can test" to be a competitor. Kozak testified that Meridian would "consider that an opportunity." Kozak Tr. at 112:15-20. Kozak proceeded to explain that "most labs who have LDTs" would switch to an FDA-cleared (i.e. IVD) product if the latter became available. *Id*. at 112:21-113:8.

Meridian next argues that the overlap in trade shows is "quite small compared to the overall market, consisting of only a handful of trade shows …." Mer. Br. at 31. Meridian ignores that Illumina attended most of the trade shows that Meridian attended with its ILLUMIGENE and ILLUMIPRO products. *Compare* Ex. 2 at 10 *with* O'Grady Decl. ¶¶ 10-14.

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[5] *See* https://wwwn.cdc.gov/clia/Resources/TestComplexities.aspx

[6] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Detail.cfm?ID=20405

5. The ILLUMINA mark is famous

Illumina has used its ILLUMINA mark since 1999, its market cap exceeds $25 billion, Ill. Br. at 8, its revenue from 2007 through September 2013 surpassed $5.5 billion, and that revenue has steadily grown. *Id*.; Possemato Decl. ¶ 42. Meridian acknowledges that Illumina has captured "70% market share in certain fields of genetic analysis." Mer. Br. at 41. Even allowing for Meridian's arguments, Illumina demonstrated that ILLUMINA is famous.

Meridian questions whether Illumina's revenue and advertising expenses relate to ILLUMINA. *Id*. at 37-38, 40. Meridian, however, concedes that ILLUMINA is Illumina's "house mark," *Id*. at 47, which is a trademark that identifies all of a company's products or services. *In re Royal BodyCare, Inc.*, 83 USPQ2D 1564, 1569 (TTAB 2007). All of Illumina's products contain the mark, Possemato Decl. ¶ 11, and Illumina prominently features the mark in its advertising and on its website. Exs. 201, 202. Meridian quibbles that, after an acquisition, there may be a transition period before Illumina applies its own branding. Mer. Br. at 37-38, n.17. That carve out would not even dent Illumina's massive revenue.

Meridian then wrongly implies that the revenue figures include "non-trademark items such as interest income, technology licensing revenue, etc." *Id*. at 37. Illumina's "interest income" is reported as a separate line item on its Statements of Operations data. *See, e.g.*, Ex. 216 at ILLUM-1930; *see also* Exs. 217–228. Further, Illumina's annual reports explain that Illumina's "revenue is primarily from two sources: product revenue and services revenue." *See, e.g.*, Ex. 221 at ILLUM-2465.

Meridian also faults Illumina for providing "no evidence whatsoever" of its sales volume in units instead of revenue. Mer. Br. at 37. But billions of dollars in sales demonstrates a significant sales volume.

Meridian argues that revenue coming from "shipments to customers outside of the United States" is irrelevant for fame. *Id*. at 38. Even if Meridian was correct, and Illumina's revenue was cut by half, its product revenue would still be over $2.7 billion.

Meridian asserts that Illumina is not famous in clinical diagnostics. *Id*. at 39. But Illumina need not show that ILLUMINA is famous for the goods described in **Meridian's** recitations (i.e., clinical diagnostic goods). *Recot, Inc. v. Becton*, 214 F.3d 1322 (Fed. Cir. 2000).

Finally, Meridian wrongly implies that fame after Meridian's priority date is irrelevant. The Board considers fame that a party achieved until the testimony period closes. *General Mills Inc. v. Fage Dairy Processing Indus. S.A.*, 100 USPQ2d 1584, 1595 n.13 (TTAB 2011).

6. Sophistication and lack of reported confusion are not determinative

Meridian argues that consumers are sophisticated and "exercise careful consideration in making purchasing decisions." Mer. Br. at 33. But as Illumina explained, even sophisticated customers are not immune from source confusion. Ill. Br. at 43.

Meridian also ignores that a buyer could be confused earlier in the decision-making process. *Id*. at 44. Even after purchase, those working in the lab could see the parties' respective goods and believe that they come from a common source. *Id*. at 44-45. Illumina also preempted Meridian's argument regarding an alleged price difference. *Id*. at 32-33.

Finally, Meridian argues that the purchasing process for the Veracode bead sets was complicated. Mer. Br. at 34. But this was just one of Illumina's commercial products, and Illumina's registrations do not require the details to which Meridian refers.

Illumina also explained that it need not show actual confusion, because the relevant test is likelihood of confusion not actual confusion. Ill. Br. at 45. Lack of reported confusion has minimal relevance, and cannot outweigh the evidence of a likelihood of confusion. *Id*.

7. Third-party registrations do not weaken Illumina's marks

Meridian argues that third-party ILLUM- and LUMI-formative registrations demonstrate that those prefixes "are commonly used in the scientific and medical fields." Mer. Br. at 43. Meridian further argues that, instead of the ILLUM or LUMI prefixes, a consumer "will look to the other elements or aspects of the mark because he will not attribute any source-identifying qualities to the commonly-used prefixes." *Id*.

Meridian must demonstrate that "customers have become so conditioned by a plethora" of ILLUM and LUMI similar marks "that customers have been educated to distinguish between different such marks on the bases of minute distinctions." *Palm Bay Imports, Inc. v. Veuve Clicquot Ponsardin Maison Fondee En 1772*, 396 F.3d 1369, 1374 (Fed. Cir. 2005). To satisfy this standard, Meridian must establish that the third-party marks are used with similar goods to those at issue here and are exposed to the relevant consumers. *Charrette Corp. v. Bowater Commc'n Papers Inc.*, 13 USPQ2d 2040, 2043 (TTAB 1989) ("any uses on unrelated goods or in unrelated fields would be irrelevant."). Because Meridian has not made this showing, the marks are irrelevant.[7]

Meridian has also not shown that any of the third party marks are as close to Illumina's marks as ILLUMIGENE and ILLUMIPRO. *Fiserv, Inc. v. Elec. Transaction Sys. Corp.*, 113 USPQ2d 1913, 1919-920 (TTAB 2015). For example, Meridian has not shown that any of the

[7] Contrary to Meridian's conclusory statement, that Illumina previously enforced its mark does not establish the requirement that relevant consumers in this case would encounter the types of goods recited in the third-party registrations Meridian raises here. *See* Mer. Br. at 42-43, n. 19.

marks combine the identical ILLUMI prefix with a descriptive suffix—such as GENE and PRO—that increases association with Illumina.

Finally, Meridian failed to establish the requisite usage and awareness of the marks. *See Palm Bay*, 396 F.3d at 1373-74. Meridian merely offers internet screen captures. This evidence does not demonstrate the extent, if any, to which the marks have been used in commerce. The evidence also fails to demonstrate any appreciable level of consumer awareness—let alone amongst relevant consumers. Therefore, the evidence is insufficient for this reason alone. *See Id.* ("where the 'record includes no evidence about the ***extent of [third-party] uses*** ... [t]he probative value of this evidence is thus minimal.'") (emphasis in original) (citations omitted).

8. Illumina's use of multiple ILLUMI marks increases a likelihood of confusion

Contrary to Meridian's misrepresentation, Illumina does not rely on a family of marks. *See* Mer. Br. at 43. Nevertheless, Illumina's other ILLUMI marks—ILLUMICODE, ILLUMINOTES and ILLUMINADX—share the same construction and are used on a variety of goods. This bolsters the likelihood that consumers encountering Meridian's ILLUMI marks—which have the same construction—would assume a connection with Illumina. *See In re Hitachi High-Technologies Corp.*, 109 USPQ2d 1769, 1774 (TTAB 2014).

9. That ILLUMINA is a house mark does not weigh against Illumina

Meridian argues that because "ILLUMINA is a house mark," confusion is "even less likely." Mer. Br. at 47. Meridian cites no authority. As Illumina explained, that ILLUMINA is a house mark makes confusion more likely. Ill. Br. at 42.

Meridian argues that "it is the company's brand that is foremost in the consumer's mind – not the names of the products that the company offers to meet a particular need." Mer. Br. at 48. Even if this assertion were true, it is irrelevant because Meridian's marks do not contain the

MERIDIAN house mark. *See Interstate Brands Corp. v. McKee Foods Corp.*, 53 USPQ2d 1910, 1914-15 (TTAB 2000) (rejecting argument that inclusion of applicant's and opposer's house marks on their respective packaging prevents confusion).

10. Coexistence of the parties' TRU-formative marks is irrelevant

Meridian misleadingly argues that "the Board considers the coexistence of third party registrations for similar marks without actual confusion as evidence that confusion is unlikely." Mer. Br. at 48 (citing *In Re Strategic Partners, Inc.*, 102 USPQ2d 1397, 1399 (TTAB 2012)).

In *Strategic Partners*, the applicant owned a registration for a mark nearly identical to the mark that the examiner rejected. *Strategic Partners*, 102 USPQ2d at 1397. For five years, that registered mark had coexisted with the cited mark. *Id*. at 1399. Therefore, the Board found that the cited mark was not confusingly similar to the rejected mark. *Id*. at 1400. By contrast, Meridian's TRU marks are not nearly identical to its ILLUMIGENE and ILLUMIPRO marks.

Contrary to Meridian's argument, the parties' TRU marks do not "present nearly identical facts" to this case. *See* Mer. Br. at 49. TRU is a descriptive term that describes the accuracy of a test. http://medical-dictionary.thefreedictionary.com/true+positive. In contrast, ILLUMI is a coined, distinctive term, and ILLUMINA is Illumina's famous house mark that it uses with its entire line of goods and services.

III. CONCLUSION

Illumina established a likelihood of confusion, and Meridian has not rebutted Illumina's showing. Therefore, the Board should cancel Meridian's ILLUMIGENE registrations and refuse Meridian's ILLUMIPRO applications.

Respectfully submitted

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Date: September 21, 2015

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CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **REPLY BRIEF OF OPPOSER/PLAINTIFF ILLUMINA, INC.** upon Applicant's counsel by depositing one copy thereof in the United States Mail, first-class postage prepaid, on September 21, 2015, addressed as follows:

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